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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/492,764	01/27/2000	Richard Jove	114205.1101	1344

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EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/492,764	Applicant(s) JOVE ET AL.	
Examiner Karen A Canella	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,19,21-27,33 and 34 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,19,21-27,33 and 34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/30/2003
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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DETAILED ACTION

Claims 1, 19 and 24 have been amended. Claims 20 and 28-32 have been canceled. Claims 33 and 34 have been added. In order to advance prosecution, the species recited in claims 26 and 27 have been rejoined for examination at this time. Claims 1, 2, 19, 21-27, 33 and 34 are pending and under consideration.

The text of Title 35, U.S. Code not found in this action can be found in a previous action.

Claims 1, 2, 19, 21-27, 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A)As drawn to new matter

Claim 1 has been amended to recite the limitation “wherein said antagonist antagonizes STAT homodimer DNA binding and wherein said antagonist noncovalently binds to a STAT polypeptide”. The instant specification provided for an assay wherein peptides were assayed for their ability to disrupt STAT3 binding activity or to bind to the SH2 domain of STAT3, thereby interfering with the SH2-pY interaction. This does not provide adequate support for the limitation of “antagonizing STAT homodimer DNA binding” because the specification only provides written description for peptides which bind to a SH2 domain of a STAT3 polypeptide, or peptides which bind to full length STAT3 and disrupt STAT3-DNA binding. Further, new claim 34 specifies that the STAT polypeptide is dimeric. The specification does not provide support for the disruption of a STAT dimer after said dimer has been formed because the disclosed experiments were directed only to the binding of the antagonist peptides to STAT monomers. One of skill in the art would have reasonably concluded that a peptide as small as a 3 or 4-mer would not be able to “break” the complex between two full length STAT monomers, or that this “breakage” could be realized under physiological conditions in a method of inhibiting the growth of cancer cells in a patient.

(B)As drawn to inadequate written description

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The instant method claims are reliant upon a genus of antagonists to STAT signaling which antagonize STAT homodimer formation and bind to a STAT polypeptide. The specification described the peptides of SEQ ID NO:12-16 as antagonists of STAT3 DNA binding and SEQ ID NO:17-19 as peptides which bind to the SH2 domain of STAT3. It is also noted that SEQ ID NO:20, 22, 24 and 25 specify that the antagonist comprises, rather than consists of a 6-mer peptide, with one residue unspecified. Thus, claim 25 encompass methods reliant on the identity of antagonists for any STAT polypeptide which minimally comprise a 6-mer peptide with one residue unassigned. SEQ ID NO:32 is a 4-mer peptide, SEQ ID NO:27, 28, 30 and 35 are antagonists comprising 4-mer peptides with one residue unassigned; SEQ ID NO: 31 is a 3-mer peptide; SEQ ID NO:34 and 36 are antagonists comprising 4-mer peptides with two residues unassigned and SEQ ID NO:37 and 38 are antagonists comprising 3-mer peptides with one residue unassigned. It is concluded that the structural constraints imposed upon the identity of the antagonists of claim 25 are minimal because the antagonists only need to minimally comprise the few amino acids dictated by the SEQ ID NO, and therefore encompass much larger polypeptide. The disclose of a very small peptide, such as a 6-mer with one residue unassigned, or smaller peptides, does not provide adequate written description of the entire genus of peptides which include proteins which are much larger than the peptides and minimally comprise the very small amino acid sequence. Further, the genus of antagonists for claims 1, 2, 19, 33 and 34 is highly variant because it encompasses molecules of any structure, not limited to peptides. The genus of antagonists for claims 1, 19, 21, 24-27, 22 and 34 is highly variant because it encompasses antagonists which bind to any STAT, not just STAT3. It is noted that there is no nexus between the binding to STAT3 and the binding to any other STAT polypeptide because each STAT polypeptide has a different amino acid sequence and therefore one of skill in the art would reasonable conclude that compounds or peptides which bind to STAT3 would not bind to STAT1, 2, 4, or 5, etc, and therefore the disclosure of peptide antagonists to STAT3 does not adequately describe the peptide antagonists to any STAT polypeptide.

Amendment of claim 1 to incorporate the limitation of "STAT3" in place of the generic "STAT" and to further incorporate the limitation of "wherein said antagonist consists of (rather than

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comprises) SEQ ID NO:20, 22, 24, 25, 26, 27, 28, 30, 31, 32, 34, 35, 36, 37 or 38 is suggested in order to overcome this rejection.

All other rejections and objections as set forth in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

2/22/2005


KAREN A. CANELLA PH.D.
PRIMARY EXAMINER